



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Seventh Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled “Seventh Annual Sentinel Initiative Public Workshop.” Convened by the Engelberg Center for Health Care Reform at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an overview of the transition from the Mini-Sentinel pilot program to the full Sentinel System and what that means for patients and other critical stakeholders. Additionally, panelists will discuss the future of the Sentinel System and opportunities to expand its medical product surveillance capabilities. This workshop will also engage stakeholders to discuss current and emerging Sentinel projects.

Date and Time: The public workshop will be held on February 5, 2015, from 9 a.m. to 4 p.m. EST.

Location: The public workshop will be held at the Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005. For additional travel and hotel information, please refer to <http://events.SignUp4.com/sentinel2015>. (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the Federal Register.)

There will also be a live Webcast for those unable to attend the meeting in person (see [Streaming Webcast of the Public Workshop](#)).

Contact Person: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6358, Silver Spring, MD 20993, 301-796-3714, FAX: 301-847-3529, email: [SentinelInitiative@fda.hhs.gov](mailto:SentinelInitiative@fda.hhs.gov).

Registration: To attend the public workshop, you must register before February 5, 2015, by visiting <http://events.SignUp4.com/sentinel2015>. You may also register for the live Webcast by visiting this Web page. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. Those without Internet access should contact Carlos Bell to register (see Contact Person). There is no registration fee for the public workshop. However, registration will be on a first-come, first-served basis because seating is limited. Therefore, early registration is recommended. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Washington Plaza Hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (202-536-3634, email: [SentinelEvent@Brookings.edu](mailto:SentinelEvent@Brookings.edu)) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast (archived video footage will be available on the Brookings Institution Web site following the workshop). Persons interested in viewing the live Webcast must register online by February 4, 2015, at 5 p.m. EST. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants but to view using one connection

per location whenever possible. Webcast participants will be sent technical system requirements and a test link in advance of the event. Prior to joining the streaming Webcast of the public workshop, it is recommended that you review these technical system requirements and test your connection.

Meeting Materials: All event materials will be available to registered attendees via email before the workshop and will be posted after the event on the Brookings Institution event Web site at <http://www.brookings.edu/health/events>.

Transcripts: Please be advised that transcripts will not be available.

Dated: October 15, 2014.

Leslie Kux,  
Assistant Commissioner for Policy.

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